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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,102	01/25/2001	Roger Craig	10069/1062	5353

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 12/30/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/770,102	CRAIG, ROGER
	<b>Examiner</b>	<b>Art Unit</b>
	Gary W. Counts	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 13 November 2002 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-13,27,28,30,32-52 and 55-76 is/are pending in the application.  
4a) Of the above claim(s) 35-50 and 55-76 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-13,27,28,30 and 32-34,<sup>,51 and 52</sup> is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other:

## **DETAILED ACTION**

### **Status of the claims**

The amendment filed November 13, 2002 is acknowledged and has been entered.

#### ***Election/Restrictions***

1. Applicant's election with traverse of the species kinases in Paper No. 13 is acknowledged. The traversal is on the ground(s) that phosphatases are sufficiently similar in action as not to impose a serious burden upon the Examiner for examination purposes. This is not found persuasive because of the reasons stated in the previous office action. Further, the enzymes are distinct and independent they are different enzymes and have unique enzyme activity and have unique structure and operate with unique substrate.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 4, 27, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Blau et al (WO 98/44350).

Blau et al disclose methods for detecting protein-protein interactions. Blau et al specifically disclose that the term proteins and polypeptides are interchangeable (p. 9). Blau et al disclose that the methods of the invention can be used to study other molecules which influence the interaction between the binding partners (p. 23, lines 11-12). Blau et al disclose the phosphorylation of one of the binding partners endows it to associate with another of the binding partners (p. 23, line 30 – p. 24 line 3). Blau et al disclose that the interactions can be detected by using reporter subunits (tag) which produce a chromogenic, fluorescent or luminescent signals. (p. 19, lines 20-27). Blau et al disclose that the reporter subunits may comprise fluorophores which are capable of detectable resonance energy transfer when they are closely associated (p. 14, lines 27-32). Blau et al disclose that the methods can be used to study agonists or antagonist of a binding interaction (p. 23).

4. Claims 1-4, 28 and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Heroux et al (US 6,312,896).

Heroux et al disclose methods for measuring the activity of enzymes. Heroux et al disclose mixing two substrates and an enzyme which catalyzes a change in the substrate molecule (for example phosphorylation of a protein) that induces the substrate

to bind to a second molecule (col 11, lines 1-62). Heroux et al disclose that these substrates can be polypeptides and that these polypeptides can contain natural and unnatural units (col 12, lines 1-32). Heroux et al also disclose that the substrates can be labeled (tagged) with a ECL labels. Heroux et al also disclose that the substrates can be immobilized on a solid support (Fig. 2). Heroux et al disclose that the invention can be used to assay an enzyme inhibitor and/or to measure the inhibitory ability of test compound.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-13, 30 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Blau et al in view of Colyer et al (US 6,465,199).

See above for teachings of Blau et al.

Blau et al differ from the instant invention in failing to teach the polypeptides comprise one or more radioactive molecules. Blau et al also fail to teach the detection of the amount binding or dissociation in the presence of the candidate modulator that is lesser or greater as compared to the amount of binding or dissociation in the absence of the candidate modulator. Blau et al also fail to teach monitoring the rate of diffusion of the fluorescent molecule.

Colyer et al disclose methods for monitoring the activity of enzymes. Colyer et al disclose the use of radioactive labels and also disclose methods for determining the activity of a candidate modulator by comparing it to controls which do not contain the candidate modulator (col 40). Colyer et al disclose the use of fluorescence correlation spectroscopy (FCS), which relies on the measurement of the rate of diffusion of a label (col 17). Colyer et al disclose that the use of such labels, controls and FCS provide for efficient means of monitoring of post-translational modification of a protein and provides for a technique in which the addition/removal of a modifying group can be monitored continuously during real time to provide a dynamic assay system that also has the ability to resolve spatial information (col 4, lines 15-20).

It would have been obvious to one of ordinary skill in the art to incorporate labels and controls as taught by Colyer et al into the method of Blau et al because Colyer et al shows that the use of such labels, controls and FCS provide for efficient means of monitoring of post-translational modification of a protein and provides for a technique in which the addition/removal of a modifying group can be monitored continuously during real time to provide a dynamic assay system that also has the ability to resolve spatial information.

7. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blau et al in view of Colyer et al as applied to claims 1, 3-13, 27, 28, 30, 32 and 51 above, and further in view of Heroux et al.

See above for teachings of Blau et al and Colyer et al.

Blau et al and Colyer et al differ from the instant invention in failing to teach the binding partner polypeptides immobilized on a solid support.

Heroux et al disclose methods for measuring the activity of enzymes. Heroux et al disclose mixing two substrates and an enzyme which catalyzes a change in the substrate molecule (for example phosphorylation of a protein) that induces the substrate to bind to a second molecule (col 11, lines 1-62). Heroux et al disclose that these substrates can be polypeptides and that these polypeptides can contain natural and unnatural units (col 12, lines 1-32). Heroux et al also disclose that the substrates can be immobilized on a solid support (Fig. 2). Heroux et al disclose that the invention can be used to assay an enzyme inhibitor and/or to measure the inhibitory ability of test compound. Heroux et al discloses that the immobilization of the polypeptide provides for a simple, accurate and reliable assay for measuring enzyme activity in a sample.

It would have been obvious to one of ordinary skill in the art to immobilize polypeptides to a solid support as taught by Heroux et al into the method of Blau et al because Heroux et al discloses that the immobilization of the polypeptides provides for a simple, accurate and reliable assay for measuring enzyme activity in a sample.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
December 16, 2002



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